UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/465,667	12/17/1999	LENNART CEDGARD	ALBIHN-W-3.3	9154

530 7590 10/30/2002

LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK
600 SOUTH AVENUE WEST
WESTFIELD, NJ 07090

EXAMINER	
AFREMOVA, VERA	
ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 10/30/2002

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/465,667	Applicant(s) Cedgart
	Examiner Vera Afremova	Art Unit 1651

-- The MAILING DATE of this c mmunication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 7, 2002*.

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *11, 12, 14-27, and 29-32* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *11, 12, 14-27, and 29-32* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 19
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 11, 12, 14-27 and 29-32 as amended are pending and under examination in the instant office action. [Paper No. 20 filed 8/07/2002]

Claims 1-10 were canceled by applicant in Preliminary amendment [paper No. 8 filed 2/05/2001]. Claim 13 was canceled by applicant [Paper No. 11 filed 5/21/2001]. Claim 28 was canceled by applicant [Paper No. 20 filed 8/07/2002].

Response to Arguments

Applicant's arguments filed 8/07/2002 have been fully considered but they are not persuasive for the reasons below.

Claim Rejections - 35 USC § 112

New matter

Claims 11, 12, 14-27 and 29-32 as amended remain rejected under 35 U.S.C. 112, *first paragraph*, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention as explained in the prior office action and for the reasons below.

The following has been explained in the prior office action:

1. Insertion of the limitation directed to a combination of two structural elements such as tablet friability range "between 0.1 and 1.0" and bacterial viability of "at least about 60 %" (see claims 11, 16, 22, 27 and 28) and insertion of the limitation directed to a combination of two

structural elements such as tablet friability range "between 0.3 and 0.5" and bacterial viability of "at least about 60 %" (see new claims 29-32) have no support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept of the use of a combination of two structural elements as presently claimed.

There is only one exemplified disclosure (example 1, page 4) wherein the viability of lactic bacteria appears to be 60 % in the tablet with inulin or fructose oligosaccharide (for example: see page 4, line 33: 100% bacterial viability minus 40% of reduction of CFU of bacteria = 60%) and the friability of the tablet of this example is 0.3 (page 4, line 30) but not the whole range as claimed. The only example 1 is not a sufficient support for the newly limited genus directed to a combination of the whole range for tablet friability such as "between 0.1 and 1.0" and the viability of bacteria such as "at least about 60 %" (see claims 11, 16, 22, 27 and 28). The only example 1 is not a sufficient support for the newly limited genus directed to a combination of the whole range for tablet friability such as "between 0.3 and 0.5" and the viability of bacteria such as "at least about 60 %" (see claims new claims 29-32). The presently claimed range for tablet friability "between 0.1 and 1.0" is said to be a conventional range for commercially acceptable products in the from of tablet (see specification page 3, lines 27-29) and the presently claimed range "between 0.3 and 0.5" is regarded by applicants as preferred friability of the tablets of the instant invention (page 3, lines 26). However, the example 1 demonstrates

only one parameter of tablet friability which is 0.3. Thus, there is no sufficient support for the newly limited genera which encompass the use of whole ranges.

This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of the limitation directed to a combination of two structural elements such as tablet friability range "between 0.1 and 1.0" and bacterial viability of "at least about 60 %" (see claims 11, 16, 22, 27 and 28) and the insertion of the limitation directed to a combination of two structural elements such as tablet friability range "between 0.3 and 0.5" and bacterial viability of "at least about 60 %" (see new claims 29-32) are considered to be the insertions of new matter for the above reasons.

With regard to the rejection above applicant appears to argue that the specification does not need to describe every possible combination of elements (see response pages 3-4). Yet, the claimed combination is missing in the as-filed specification. The specification does not discloses a range of bacterial viability "at least 60 %" which has the meaning of viability being from 60% and more or being from 60% to 100%. There is no generic disclosure related to specific amounts of viability. The only example demonstrates one value of 40 % reduction of bacterial viability after compressing the tablets with inulin wherein one value of 60% might be derived from

calculations. Thus, the combination of two claimed elements such as bacterial viability being more than 60% and tablet friability between 0.1-1.0 is not present in the as-filed specification. Therefore, the claimed combination of ranges is a new matter.

2. The rejection with respect to insertion of limitation such as "the total amount bacteria provided is between 0.5-50% by weight with 40-99.5% by weight of inulin, 0-20% by weight microcrystalline cellulose, 0-20% by weight of calcium diphosphate and 0-15% by weight of starch" has been withdrawn because of cancellation of claim 28..

Indefinite

Claims 11, 12, 14-27 and 29-32 as amended remain rejected under 35 U.S.C. 112, ***second paragraph***, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention as explained in the prior office action and for the reasons below.

Claims 11, 16, 22 and 27-32 remain indefinite with respect to the phrase "a force sufficient" or with regard to the step employing "a force sufficient" as explained in the prior office action.

Applicant argues that the claim provides objective endpoints which are bacterial viability and tablet friability and that one could determine what force is sufficient based on the value of "endpoints" (see response page 4, last par.). However, the claimed/argued "endpoints" are results

but not starting parameters. The claimed/argued "endpoints" are success of the method wherein it is uncertain what is actually done or what "force" is applying to achieve these successful endpoints as argued.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11, 12, 14-27 and 29-32 as amended remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,531,989 [C] taken with US 4,806,368 [B-16], US 5,536,526 [A-16], US 5,422,346 [B], US 4,396,631 [A] and US 4,021, 545 [E] as explained in the prior office action and for the reasons below.

The claims are directed to a method for producing tablets with live bacteria comprising step of mixing live bacteria with fructose oligosaccharide or inulin and step of pressing the mixture into tablet with viable bacteria. The final tablet has a particular friability within 0.1-1.0 and bacterial viably. The bacterial viability after compressing tablets is about 60%. Some claims are/are further drawn to the use of particular species of lactic bacteria in the mixture such as *Lactobacillus bulgaricus, Lactobacillus plantarum, Streptococcus thermophilus or Bifidobacterium animalis*. Some claims are further drawn to the use of fructose oligosaccharide

or inulin at concentration 40-99.5% in the tablet. Some claims are further drawn to incorporation of additives into the tablet such as starch or calcium diphosphate.

The cited references are relied upon as explained in the prior office action and repeated herein.

US 5,531,989 [C] teaches a method for producing compositions with live lactic bacteria comprising step of mixing live lactic bacteria with fructose oligosaccharide or inulin and step of producing dry composition in the form of agglomerates wherein the final product comprises about 40-60 % by weight of inulin and/or fructose oligosaccharide and about 0.1-20% by weight of live lactic bacteria of *Lactobacillus sp.* and /or *Bifidobacterium sp.* including *L. bulgaricus* and *L. plantarum* (col. 13, lines 38-50 and col. 4, lines 1-30). The method of the cited patent clearly teaches a production of viable bacterial product. The method of the cited patent clearly teaches the use of live lactic bacteria and inulin in the agglomerated product and the packaging of the product in a suitable container. But the cited patent is silent with regard to friability of the final product.

However, US 5,536,526 [A-16] is relied upon for the teaching of tableting techniques and for the disclosure related to criteria of tablet quality such as, for example: friability between 0% and 3% which is considered to be acceptable for most drug and food tablets (col. 4, lines 7-10).

The cited patent US 4,806,368 [B-16] demonstrates that hard tablets with viable bacteria are known and they have been made. US 4,806,368 teaches a method of making tablets with live lactic bacteria including bacteria belonging to genera of *Lactobacillus* and *Bifidobacterium*

(abstract) and other additives such as dietary fibers, calcium phosphate (abstract or table at col. 3), cellulose (cl.1, line 26-28), etc. The cited patent clearly teaches that the viability of lactic bacteria and the extended shelf life of lactic bacteria during storage is considerably better for the bacterial compositions in the form of tablets than in the from of dry powder (col. 9, example 4) and the viability appears to be more than 60% after 3 months of storage (table IV, col. 9). The cited patent also teaches that the tablets with live lactic bacteria were compressed to a hardness of 11-14 kg (col. 3, line 65). The cited patent teaches that use of dietary fibers such as apple fibers, for example, but it is lacking particular disclosure related to the use of the fructo oligosaccharide such as inulin in the tablets with live lactic bacteria.

However, the use of inulin is taught by US 5,531,989 [C] as explained above.

In addition, US 5,422,346 [B] discloses the use of fructose oligosaccharide or inulin in the method for producing tablets and it teaches that inulin is compressed into tablets without the need of additional tableting material such as starch, for example : col. 8, lines 41-44. The cited patent also teaches that inulin is a growth promoting substrate of lactic bacteria such as *Bifidobacterium sp* and that pathogenic bacteria can not utilize inulin unlike beneficial bacteria in the gut of animals (col. 18, lines 25-37).

In addition, US 4,396,631 [A] teaches a method for method for producing tablets with live lactic bacteria by step of mixing live lactic bacteria with polysaccharide such as starch, for example, and/or other materials/additives suitable for tablets and step of pressing the mixture with a force sufficient to from tablets with viable bacteria. The cited patent clearly discloses that

lactic bacteria retain high viability ($2x10^8$ cfu) after formation of compressed tablets as well as during storage of compressed tablets (col. 4, example 1). But the cited method is lacking the disclosure of fructose oligosaccharide or inulin in the mixture with live lactic bacteria intended for forming compressed products or tablets.

Further, US 4,021, 545 [E] teaches a method for producing tablets comprising both inulin and other additives such as starch or calcium diphosphate in one tablet (col. 5, example 4).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to provide dry products containing live or viable lactic bacteria and inulin which are characterized by commercially acceptable friability and/or hardness because hard tablets with live lactic bacteria are known in the prior art and they have been commercially available as adequately demonstrated by US 4,806, 368 [B-16] and by US 5,531,989 [C]. One ordinary of skill in the art would have been motivated to modify the form of packaging from powder to tablet because the viability of lactic bacteria during storage is considerably better for dry products in the form of tablets than in the form of powder as taught by the prior art {US 4,806, 368 [B-16]}. In addition, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to substitute inulin for starch in the lactic bacteria containing tablets in the method of US 4,396,631 [A] with a reasonable expectation of success in obtaining pressed or compressed tablets since the use of inulin allows for the exclusion of additional tableting binders such as starch, for example, as taught by US 5,422,346 [B], thus,

decreasing the cost of the tableting process. Accordingly, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning (see response page 5, par. 4), it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

The applicant' argument that there is no suggestion or motivation to combine the cited references (see response page 5, last par.) is not found convincing. The prior art demonstrates the use of inulin in dry agglomerates containing viable lactic bacteria {US 5,531,989 [C]}, the use of inulin in pharmaceutical tablets {US 4,021, 545 [E]} and the use of lactic bacteria in dry hard tablets {US 4,806, 368 [B-16]}. The cited prior art provides motivation to use inulin in bacterial tablets as a growth promoting agent for beneficial bacteria and as a superior binder in the pharmaceutical tablets {US 5,422,346 [B]}. The cited prior art provides motivation to make

viable bacterial product in a form of tablets because bacterial tablets have better viability than bacterial loose powder {US 4,806, 368 [B-16]}.

Applicant argues that the cited art does not provides motivation to use inulin as a "sustaining" agent during tablet compression (page 6, par. 2). However, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Applicant's argument that the cited prior art dose not provide teaching, suggestion or motivation on how to obtain tablets with 60 % viable bacteria and friability of 0.1-1.0 (page 6, par. 1) is not found convincing because the claimed invention is indefinite with regard to "a force sufficient" to obtain a tablet with the claimed parameters. Moreover, applicant appears to argue that one of skill in the art could readily determine how to achieve this goal (see response page 4, last three lines).

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova,

Art Unit 1651

October 24, 2002.

V.A.

IRENE MARX
PRIMARY EXAMINER